# IN THE UNITED STATES COURT OF FEDERAL CLAIMS

**OFFICE OF SPECIAL MASTERS**
**No. 08-781V**
**Filed: May 27, 2011**
**To be Published**

| | | |
|---|---|---|
| * * * * * * * * * * * * * * * * * * * * * * * * | | |
| MELISSA D. PARSLEY, as the legal representative of her minor son, Corey Parsley, | * | Intussusception; Rotavirus; RotaTeq Vaccine; Six Month Requirement; Residual Effect or Complication; Epidemiology |
| Petitioner, | * | |
| v. | * | |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | |
| Respondent. | * | |
| * * * * * * * * * * * * * * * * * * * * * * * * | | |

Curtis R. Webb, Esq., Twin Falls, ID, for petitioner.
Voris E. Johnson, Esq., U.S. Dept. of Justice, Washington, DC, for respondent.

## DECISION[1]

**Vowell**, Special Master:

On October 31, 2008, Melissa Parsley ["Ms. Parsley" or "petitioner"] filed a Petition for Vaccine Compensation in the National Vaccine Injury Compensation Program ["the Program"],[2] on behalf of her son, Corey Parsley ["Corey"]. The petition

[1] Because this decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to delete medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will delete such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 [the "Act"]. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2006).

alleges that the RotaTeq[3] vaccination Corey received on March 20, 2007, caused an intussusception[4] diagnosed on April 7, 2007. Petition, ¶¶ 4, 11, 12. On December 22, 2009, petitioner filed the report of her medical expert, Dr. Mark Thoman, as Petitioner's Exhibit ["Pet. Ex."] 8. On January 28, 2009, respondent filed her Vaccine Rule 4 report recommending that compensation be denied. The reports of respondent's experts, Drs. Stephen B. Hanauer and Neal Halsey, were filed on May 12, 2010, as Respondent's Exhibits ["Res. Exs."] A and C, respectively.

This case was reassigned to me on March 31, 2010. I conducted an entitlement hearing on November 15 and 16, 2010, in Washington, DC. Doctors Thoman, Hanauer, and Halsey all testified in person. Post-hearing briefs from petitioner and respondent were filed on January 6, 2011, and respondent filed a response to petitioner's brief on January 21, 2011. Petitioner chose not to file a responsive brief. The record is now complete and the case is ripe for decision.

To be eligible for compensation under the Vaccine Act, a petitioner must either demonstrate a Vaccine Table[5] injury, to which a statutory presumption of causation attaches, or prove by a preponderance of the evidence that a vaccine listed on the Vaccine Injury Table caused or significantly aggravated an injury [an "off-Table" injury]. *Althen v. Sec'y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Grant v. Sec'y, HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Ms. Parsley does not contend that Corey suffered a "Table" injury.[6] Therefore, in order to prevail, she must demonstrate by preponderant

---

[3] RotaTeq is a live, oral pentavalent rotavirus vaccine that protects infants and young children from severe acute gastroenteritis (*i.e*., diarrhea) caused by rotavirus infections. PHYSICIAN'S DESK REFERENCE 2074 (61st ed. 2007). *See also* Transcript ["Tr."] at 8-11, 65, 150-52, 171-73.

[4] In layman's terms, an intussusception occurs when part of the intestine telescopes into itself, causing a blockage. Tr. at 173-74; *see also* DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (31st ed. 2007) ["DORLAND'S"] at 969.

[5] A "Table" injury is an injury listed on the Vaccine Injury Table, 42 C.F.R. § 100.3 (2010), corresponding to the vaccine received within the time frame specified.

[6] The Table was amended to include all rotavirus vaccines, without specific associated Table injuries, in 1999. *See* Addition of Vaccines Against Rotavirus to the Program, 64 Fed. Reg. 40517 (July 27, 1999). It was amended again to identify intussusception as a Table injury for live oral rhesus-based rotavirus vaccine. *See* Revisions and Additions to the Vaccine Injury Table, 67 Fed. Reg. 48558 (July 25, 2002). Intussusception as a Table injury associated with live oral rhesus-based rotavirus vaccine was subsequently removed from the Table. *See* Removal of Separate Category for Vaccines Containing Live, Oral, Rhesus-Based Rotavirus From the Vaccine Injury Table, 73 Fed. Reg. 59528 (Oct. 9, 2008) (codified at 42 C.F.R. § 100.3 (2010)). It was removed from the Table because manufacturers removed live oral rhesus-based rotavirus vaccines from the market, and the Centers for Disease Control ["CDC"] recommended that this vaccine no longer be routinely administered to children. *Id.* at 59529. The rhesus-based rotavirus vaccine, known as RotaShield, is discussed *infra*, as petitioner relied on the known association between RotaShield and intussusception to establish biological plausibility for her theory that the RotaTeq vaccine Corey received could also cause intussusception. There is no Table injury for any non-rhesus-based rotavirus vaccine, including RotaTeq, the type of rotavirus vaccine that Corey received. *See* 42 C.F.R. § 100.3 (2010).

evidence "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen,* 418 F.3d at 1278. *See also Hines v. Sec'y, HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991).

After considering the record as a whole,[7] I find that Corey received his second rotavirus vaccination on March 20, 2007; that the vaccine was administered in the United States; and that the RotaTeq vaccine is one covered by the Vaccine Act. I hold that petitioner has failed to establish by preponderant evidence that Corey suffered residual effects from the intussusception for more than six months. Assuming, *arguendo*, that he did, I also hold that petitioner failed to establish that Corey's intussusception was caused by the RotaTeq vaccine. Furthermore, respondent produced preponderant evidence of an alternate cause for the intussusception. Accordingly, Ms. Parsley's petition for compensation is denied.

## I. Legal Standards for Evaluating Off-Table Causation Claims.

To establish legal cause in an off-Table case, Vaccine Act petitioners must establish each of the three *Althen* factors: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a proximate temporal relationship between vaccination and injury. 418 F.3d 1274, 1278 (Fed. Cir. 2005). The applicable level of proof is the "traditional tort standard of 'preponderant evidence.'" *Moberly v. Sec'y, HHS*, 592 F.3d 1315, 1322 (Fed. Cir. 2010) (citing *de Bazan v. Sec'y, HHS*, 539 F.3d 1347, 1351 (Fed. Cir. 2008); *Pafford v. Sec'y, HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Capizzano v. Sec'y, HHS*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *Althen,* 418 F.3d at 1278). The preponderance standard "requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring) (internal quotation and citation omitted).

An alternate formulation of the causation requirement in off-Table cases is the "Can it cause?" and "Did it cause?" inquiry used in toxic tort litigation. Prong 1 of *Althen* has been characterized as an alternative formulation of the "Can it cause?" query. Prong 2 of *Althen*, the requirement for a logical sequence of cause and effect between the vaccine and the injury, has been characterized as addressing the "Did it cause?" query. *See Pafford v. Sec'y, HHS*, No. 01-165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). Even if a vaccine has been causally associated with an injury, petitioner must still establish facts and circumstances that make it more likely than not that the vaccine

[7] *See* § 300aa–13(a)(1) ("Compensation shall be awarded...if the special master or court finds on the record as a whole..."); *see also* § 300aa–13(b)(1) (indicating that the court or special master shall consider the entire record in determining if petitioner is entitled to compensation).

caused his particular injury. The third *Althen* factor is subsumed into the "Did it cause?" inquiry.

Regardless of whether a case is analyzed under *Althen* or the "Can it cause?" formulation, petitioners are not required to establish identification and proof of specific biological mechanisms, as "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Althen*, 418 F.3d at 1280. The petitioner need not show that the vaccination was the sole cause, or even the predominant cause, of the injury or condition; showing that the vaccination was a "substantial factor"[8] in causing the condition and was a "but for" cause are sufficient for recovery. *Shyface v. Sec'y, HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999); *see also Pafford,* 451 F.3d at 1355 (petitioner must establish that a vaccination was a substantial factor and that harm would not have occurred in the absence of vaccination). Petitioners cannot be required to show "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect...." *Capizzano*, 440 F.3d at 1325. Causation is determined on a case by case basis, with "no hard and fast *per se* scientific or medical rules." *Knudsen v. Sec'y*, *HHS,* 35 F.3d 543, 548 (Fed. Cir. 1994). Close calls regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280. *But see Knudsen*, 35 F.3d at 550 (when evidence is in equipoise, the party with the burden of proof fails to meet that burden).

The medical theory must be a reputable one, although it need only be "legally probable, not medically or scientifically certain." *Knudsen,* 35 F.3d at 548-49. The Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, likewise requires that courts determine expert opinions to be reliable before they may be considered as evidence. "In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." 509 U.S. 579, 590 (1993) (footnote omitted). The Federal Circuit has stated that a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly,* 592 F.3d at 1324.

Circumstantial evidence and medical opinions may be sufficient to satisfy *Althen's* second prong. *Capizzano*, 440 F.3d at 1325-26. Opinions of treating physicians may also provide the logical connection. *See Andreu v. Sec'y, HHS*, 569 F.3d 1367, 1376 (Fed. Cir. 2009); *see also Moberly,* 592 F.3d at 1323; *Capizzano*, 440 F.3d at 1326.

---

[8] The recently approved Restatement (Third) of Torts has eliminated "substantial factor" in the factual cause analysis. § 26 cmt. j (2010). Because the Federal Circuit has held that the causation analysis in Restatement (Second) of Torts applies to off-Table Vaccine Act cases (*see Walther v. Sec'y, HHS*, 485 F.3d 1146, 1151 (Fed. Cir. 2007); *Shyface v. Sec'y, HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)), this change does not affect the determination of legal cause in Vaccine Act cases: whether the vaccination is a "substantial factor" is still a consideration in determining whether it is the legal cause of an injury.

The requirement of temporal connection necessitates a showing that the injury occurred in a medically or scientifically reasonable period after the vaccination, not too soon (*see de Bazan*, 539 F.3d at 1352) and not too late (*see Pafford*, 451 F.3d at 1358).

In Vaccine Act cases, special masters are frequently confronted with expert witnesses with diametrically opposed positions on causation. When experts disagree, many factors influence a fact-finder to accept some testimony and reject other contrary testimony. As the Federal Circuit noted, "[a]ssessments as to the reliability of expert testimony often turn on credibility determinations, particularly in cases ... where there is little supporting evidence for the expert's opinion." *Moberly*, 592 F.3d at 1325-26. Objective factors, including the qualifications, training, and experience of the expert witnesses; the extent to which their proffered opinions are supported by reliable medical research and other testimony; and the factual basis for their opinions are all significant factors in determining what testimony to credit and what to reject.

As the Court of Federal Claims noted:

> As fact-finders, Special Masters, like juries, are often faced with the "battle of the experts" when it comes to interpreting facts. And as fact-finders, they may find that truth lies somewhere in between the opposing, uncompromising views of the partisan experts. Expert opinion testimony is just opinion, and the fact-finder may weigh and assess that opinion in coming to her own conclusions.... A fact-finder, especially one with specialized experience such as a Special Master, can accept or reject opinion testimony, in whole or in part. When the evidence is in, and it is time to apply the facts to the law, the expert's role is over. Partisan testimony then gives way as the Special Master evaluates the testimony in light of the entire record, based on reasonable inferences born of common experience or the product of special expertise.

*Sword v. United States*, 44 Fed. Cl. 183, 188-89 (1999) (citations omitted); *see also Moberly*, 592 F.3d at 1325 ("Weighing the persuasiveness of particular evidence often requires a finder of fact to assess the reliability of testimony, including expert testimony, and we have made clear that the special masters have that responsibility in Vaccine Act cases.") (citations omitted).

Bearing these legal standards in mind, I turn to the evidence presented in this case.

## II. Relevant Medical History.

The facts of Corey's medical history are not in dispute. He was a healthy baby who received his first dose of the RotaTeq vaccine on January 15, 2007, without

apparent ill effects. Pet. Exs. 3, p. 19; 4, pp. 1-4.[9] Prior to receiving his second rotavirus vaccination at about five months of age,[10] Corey was generally a well child. *See* Pet. Exs. 3, pp. 1-2, 4; 4, pp. 1-4.

On March 20, 2007, Corey received a second dose of RotaTeq vaccine at a well child checkup at his pediatrician's office. Pet. Ex. 3, pp. 5, 19. Twelve days later, on April 1, 2007, Ms. Parsley brought Corey to the Highlands Regional Medical Center of Eastern Kentucky ["HRMC"]. Pet. Ex. 5, pp. 1-2. Corey was fussy, had a fever, and had been pulling at his ear. *Id*. Corey was diagnosed with otitis media[11] and prescribed amoxicillin.[12] Pet. Exs. 5, pp. 1-2; 6, p. 20. Corey did well for approximately the next two days.[13] Pet. Ex. 3, p. 7.

On April 5, 2007, Ms. Parsley took Corey to his pediatrician. Pet. Ex. 3, p. 7. She reported the emergency room visit four days earlier, the otitis media diagnosis, and a history of poor appetite, vomiting, and diarrhea for two to three days. *Id.* The physician instructed Ms. Parsley to give Corey Pedialyte and lactose-free formula, and to call if the vomiting persisted. *Id*.

Because Corey's vomiting persisted throughout that day, Ms. Parsley took Corey to the emergency room at HRMC the night of April 5, 2007. Pet. Exs. 5, p. 3; 6, p. 20. Corey was diagnosed with a viral illness and was admitted to HRMC for nausea, vomiting, diarrhea, and hypersomnolence either that evening or early the next morning.[14] Testing showed blood in Corey's stool and bacteria in his urine. Pet. Ex. 5,

---

[9] The same medical test results often appear in more than one record. Citations herein may include only one of the several places where a record appears.

[10] Some of the medical records incorrectly reflect that Corey was 16 months old when he was hospitalized in April, 2007. *See, e.g*., Pet. Ex. 5, p. 5 (top of form). He was actually just over five months old at the time. *See* Tr. at 136.

[11] Otitis media is inflammation of the ear, often accompanied by pain and fever, commonly referred to as an "ear infection." DORLAND'S at 1371-72.

[12] Amoxicillin is an antibiotic "effective against a broad spectrum of gram-positive and gram-negative bacteria." DORLAND'S at 66.

[13] The records reflect conflicting histories. On April 5, 2007, petitioner told Corey's pediatrician that he had experienced vomiting and diarrhea for the "past 2-3 days." Pet. Ex. 3, p. 7. On April 7, 2007, she told doctors at Cabell Huntington Hospital that after the April 1, 2007 HRMC visit, Corey "did well until 4/5/2007 at which time he developed diarrhea and emesis and seemed less interactive than normal per mom." Pet. Ex. 6, p. 20; *see also* Pet. Ex. 6, p. 1 (4/7/2007 note recording "2 day" history of vomiting and diarrhea), 18 (noting vomiting and bloody stools "since 4/5/07"). On April 6, 2007, Corey's grandmother told the doctor at HRMC that "the symptoms started yesterday morning so they have been occurring for approximately 1 day." Pet. Ex. 5, p. 5.

[14] The records are also in conflict here. Some records from HRMC reflect that Corey was seen in the emergency department on April 5, 2007, at 22:48 and then sent home. Pet. Ex. 5, pp. 3-4, 12-13. Other records from HRMC reflect that Corey was admitted on April 5, 2007. Pet. Ex. 5, pp. 5-9, 14-18. The parties stipulated that Corey was admitted to HRMC on April 6, 2007. Joint Submission, filed Nov. 1, 2010, at 2.

pp. 6, 15, 17. An abdominal x-ray taken in the afternoon of April 7, 2007, disclosed dilated loops of small bowel, indicating a possible bowel obstruction. Pet. Ex. 5, p. 9. Based on these findings, Corey was transferred to Cabell Huntington Hospital ["CHH"] later that same afternoon. *See* Pet. Exs. 5, p. 10; 6, pp. 1, 5.

On or about April 7, 2007, 18 days after his second RotaTeq vaccine, Corey was diagnosed with intussusception. Pet. Ex. 6, p. 12. The intussusception was successfully reduced by a barium enema.[15] *See id.*, pp. 26, 31. However, because of a concern about Corey's ileocecal[16] valve, he remained in the hospital until April 9, 2007. *See id.*, p. 26. Stool cultures were positive for *Clostridium difficile*,[17] and Corey was placed on Flagyl[18] to treat it. Pet. Ex. 6, pp. 12, 29, 31, 74.

On August 6, 2008, about 16 months after he was discharged from CHH, Corey returned to the HRMC emergency room with vomiting and mild diarrhea. Pet. Ex. 7, p. 1. His history of intussusception was noted, and, although an abdominal x-ray revealed no sign of intussusception, Corey was admitted overnight for observation. *Id*. Corey has never had a recurrence of intussusception. Tr. at 22, 140, 184.

## III. Contested Matters.

There are two contested matters in this case. A finding against petitioner on either is fatal to her case for compensation. The first is whether the RotaTeq vaccine was the cause of Corey's intussusception. In addition to contesting petitioner's case on all three *Althen* prongs, respondent proffered evidence of an alternate cause for Corey's intussusception.

The second contested matter is whether an increased risk of a subsequent intussusception, without an actual subsequent intussusception, can satisfy the requirement that a vaccine injury must persist for at least six months.[19] Absent a

---

[15] A barium enema is a procedure in which a contrasting agent is injected into the intestine. DORLAND'S at 629. Although barium enemas are primarily performed for diagnostic purposes, they are also used to treat intussusception. *See* Tr. at 178.

[16] The ileocecal valve marks the point where the small intestine joins the large intestine. It is the most common location for an intussusception to occur, and was where Corey's intussusception was located. *See* Tr. at 175-76, 188.

[17] *Clostridium difficile* (referred to in the transcript as "C diff") is a species of bacteria that causes an infection of the colon, manifested by diarrhea, in patients recovering from antibiotic therapy. DORLAND'S at 380. Receipt of antibiotics, such as the antibiotic Corey received to treat his ear infection, kills off some of the helpful bacteria in the colon, allowing the *Clostridium difficile* bacteria to proliferate in the colon, where they produce a toxin that causes diarrhea. Tr. at 155, 188-89.

[18] Flagyl is the trade name for metronidazole, an antibiotic. DORLAND'S at 722.

[19] Alternatively, petitioner could have demonstrated that Corey was hospitalized and treated surgically, establishing the two conditions serving as an exception to the six month requirement. The parties have

determination that an increased risk of future complications qualifies Corey as having "suffered the residual effects or complications of such illness, disability, injury, or condition," petitioner cannot meet the requirement that the ill effects of a vaccine must persist for six months. Thus, she would not be entitled to compensation for Corey's injury. *See* § 300aa-11(c)(1)(D)(i). For convenience, I refer to this as petitioner's "residual effects" theory. I conclude that an increased risk of recurrence without an actual recurrence of a condition is not medically recognized as a "residual effect" and is not a residual effect within the meaning of § 300aa-11(c)(1)(D)(i) of the Vaccine Act.

Because some understanding of intussusception and its causes is helpful in understanding both the vaccine causation case and the residual effects theory, I begin with background information on intussusception, followed by similar information on rotavirus and the disease process that occurs in natural rotavirus infections, before considering the causation theories advanced in this case.

All three expert witnesses provided focused and helpful testimony. Doctor Thoman's[20] testimony clearly explained his causation theory and the factors he considered important in demonstrating biological plausibility, a logical connection, and appropriate timing between the vaccine and the injury. Doctor Hanauer's[21] expertise in gastroenterology is extensive. He provided the most cogent testimony on the mechanics of intussusception. Doctor Halsey's[22] expertise in epidemiology was of central importance in assessing the applicability of various epidemiological studies, the significant differences in the three types of rotavirus vaccines, and in explaining why an increased risk of intussusception after a first vaccine does not mean an increased risk

---

agreed that the barium enema was not a "surgical procedure" within the meaning of § 300aa-11(c)(1)(D)(iii) of the Vaccine Act. *See* Order filed May 25, 2010.

[20] Doctor Thoman is board certified in pediatrics and medical toxicology. He served in the Public Health Service for two years before returning to Iowa, where he had an active clinical practice until 2000. Although primarily a pediatrician, he also saw adult patients. In 2000, he became the medical director for an Iowa county hospital. He published one case report in 1985 on an intussusception after an organophosphate overdose. Tr. at 4-6, 28-29; *see also* Curriculum Vitae ["CV"] of Dr. Thoman, Pet. Ex. 9.

[21] Doctor Hanauer is board certified in gastroenterology and internal medicine. He is the Chief of Gastroenterology at the University of Chicago Medical Center, where he maintains a heavy patient load. He is also a full professor in the medical school there. He has extensive publications in the area of inflammatory diseases of the intestinal system and is an active peer reviewer for several medical journals. Although primarily an adult gastroenterologist, he sees and treats both adult and pediatric patients. Tr. at 168-71; *see also* CV of Dr. Hanauer, Res. Ex. B.

[22] Doctor Halsey is board certified in pediatrics and pediatric infectious diseases. He is a professor at Johns Hopkins University in both the medical and public health schools, primarily teaching courses about vaccines. Early in his career, he worked for the CDC's Epidemic Intelligence Service. He served as an attending physician in Johns Hopkins' pediatric infectious disease group for 25 years. Most of his time is devoted to research on vaccines, vaccine preventable disease, and vaccine safety in the last 10 years. He has over 200 peer reviewed publications, with a substantial number of these related to vaccines and vaccine safety. Tr. at 60-62, 64; *see also* CV of Dr. Halsey, Res. Ex. D.

after a subsequent vaccination. Additionally, his involvement in the RotaShield vaccine studies and RotaShield's subsequent withdrawal from the market provided some unique insights into that process. Although I ultimately concluded that respondent's witnesses were better qualified, more strongly supported by the medical evidence, and thus more persuasive than Dr. Thoman, he was a credible witness who sincerely endeavored to assist the court in deciding the matters in controversy.

A. Causation.

1. Background Information.

a. Intussusception.

A precise biological cause for intussusception is not identified in most cases of intussusception in children. Tr. at 122; *see also* S. Kitagawa, et al., *Intussusception in children*, UPTODATE (Jan. 12, 2010) ["Kitagawa"], Res. Ex. A1 at 1. However, most physicians believe that intestinal structural problems may be aggravated by the swelling of lymph tissue in response to exposure to various pathogens, mechanically facilitating one portion of the intestine folding into a more distal portion, causing a blockage. *See, e.g.*, Tr. at 175-77; U. Parashar, et al., *Trends in Intussusception-Associated Hospitalizations and Deaths Among US Infants*, PEDIATRICS 106(6): 1413-21 (2000), Res. Ex. A2 at 1413; D. Spiro, et al., *Association Between Antibiotic Use and Primary Idiopathic Intussusception*, ARCH. PEDIATR. ADOLESC. MED. 157: 54-59 (2003), Res. Ex. A3 at 54.

The largest collection of lymphoid tissue in the body is found in the ileum, where the small intestine joins the large intestine. In young children, the lymphoid aggregates[23] in this area are enlarged, producing a condition called lymphoid hyperplasia. Tr. at 175. Swelling of the ileum's lymphoid tissue causes a narrowing of the passage between the small and large intestines. Pronounced swelling can lead to the prolapse of the small intestine into the colon, causing an intussusception. Tr. at 175-76. Less commonly, a polyp or any kind of thickening of the gut tissue could create a leading edge, permitting the telescoping of the intestine that causes intussusception. Tr. at 176.

Intussusception most commonly occurs in children between six months and two or three years of age.[24] Tr. at 23, 178-79. This time period corresponds to the

[23] What are called lymph nodes elsewhere in the body are called lymphoid aggregates in the digestive tract. Tr. at 175.

[24] The background rate of intussusception is 1-4 per 1,000 live births (Tr. at 137), but the incidence varies by age. The peak incidence is in children 5-10 months of age. *See* M. Cortese, *Estimates of Benefits and Potential Risks of Rotavirus Vaccination in the United States*, slide presentation from the Oct. 28, 2010 CDC Advisory Committee on Immunization Practices ["ACIP"] Meeting ["Cortese"], filed as Res. Ex. H, at 14.

introduction of new foods and exposure to a variety of pathogens never before encountered, explaining the enlarged lymphoid aggregates in children of this age. The lymphoid tissue in older children becomes less prominent, and intussusceptions in older children are therefore rare. Tr. at 179, 194.

The most common risk factors for intussusception include viral illnesses, such as those that cause diarrhea; upper respiratory tract infections; and ear infections. Illnesses such as these stimulate the immune system, resulting in lymphoid tissue swelling. Tr. at 50, 175-76, 179.

The medical history for the period immediately preceding the intussusception frequently includes diarrhea, although it is considered related to, but not causal of, the intussusception. Tr. at 176-77. Intussusception itself does not ordinarily cause diarrhea. Rather, diarrhea is a symptom of the viral or bacterial illness that precipitates the swelling of lymphoid tissue, leading to the intussusception. Presenting symptoms include abdominal pain, distention, and vomiting. The intestinal blockage caused by an intussusception often stops bowel movements. If the intussusception causes damage to or death of a piece of an intestine, bloody stools may result. Tr. at 135-36, 139, 177-78.

Most cases of intussusception are successfully treated with some type of enema. When employed, barium enemas are successful in more than 50% of cases. *See* Tr. at 178; J. DiFiore, *Intussusception*, SEMINARS IN PEDIATR. SURG. 8(4): 214-220 (1999) ["DiFiore"], Res. Ex. C6 at 217. Other treatments include the introduction of other fluids or air into the intestine to push the prolapsed portion back into place. Occasionally, either because a barium enema or other treatment was unsuccessful or because the intussusception was not diagnosed before portions of the intestine died, surgery is necessary to treat the condition.[25] Tr. at 178.

About 10-11% of children who experience one intussusception experience a second. Of those who experience a second intussusception, about 90% occur in close temporal relationship to the first. Tr. at 23, 53, 140-41, 186. When an intussusception is successfully reduced by barium enema, the risk of a second intussusception is higher than when the initial intussusception was treated by surgery. *See* Tr. at 54; DiFiore, Res. Ex. C6 at 218. The reduced risk after surgery is attributed to the surgical removal or fixation of the tissue predisposed to prolapse, because a second intussusception is likely caused by the same process that produced the first. Tr. at 140-41, 186; *see also* C. Yang, et al., *Recurrence of Intussusception in Childhood,* ACTA PAEDIATR. TW. 42(3): 158-61 (2001), Pet. Ex. 24 at 160. After an intussusception is reduced, most children, like Corey, recover completely. *See* Tr. at 186; DiFiore, Res. Ex. C6 at 218.

---

[25] As discussed in more detail *infra*, this surgical treatment for intussusception resulted in the amendment of the Vaccine Act in 2000 to provide for an exception to the requirement that the vaccine-caused condition must persist for at least six months before compensation may be awarded.

b. Natural Rotavirus Infections.

Rotavirus infections primarily affect children. Tr. at 65. They are the most common cause of gastroenteritis (infectious diarrhea) worldwide. The primary symptom is diarrhea, with or without vomiting, but upper respiratory illnesses occur in about 30% of cases. Tr. at 171, 173, 190. In the United States, for children under two years of age, rotavirus infections account for about 10% of all visits to doctors and about 50% of all hospitalizations. Tr. at 172.

Symptoms of rotavirus infections occur within one or two days of exposure. Tr. at 57-58, 191. Infections are usually self-limited, and commonly last between three and five days. Tr. at 191. However, when dehydration occurs, these infections can be very serious, accounting for 15-30% of deaths of young children worldwide. Tr. at 172-73.

Although Dr. Thoman characterized the evidence on whether natural rotavirus infections can cause intussusception, as conflicting, he agreed that several of petitioner's exhibits filed with his report discussed the inability to detect any increased risk of intussusception after natural rotavirus infections.[26] Tr. at 31-35. He acknowledged that the statement in his expert report that natural rotavirus causes intussusception was "[p]robably a bit strong," but stated that this opinion was based on his clinical experience. Tr. at 35. Doctor Thoman had earlier testified that he had treated 6-12 patients for intussusception during his career. Tr. at 7, 24. Doctor Halsey testified that natural rotavirus infections did not appear to cause intussusception, but noted that this was puzzling, given the gastrointestinal symptoms the virus produces. Tr. at 87.

2. Rotavirus Vaccines and Intussusception Risks.

a. Overview of Petitioner's Causation Theory.

There is virtually no direct evidence that the RotaTeq vaccine causes intussusception. Therefore, Dr. Thoman relied on evidence of increased risk from two other rotavirus vaccines, RotaShield and Rotarix, to establish biological plausibility for RotaTeq presenting a similar increased risk. He primarily relied on: (1) evidence surrounding the withdrawal of RotaShield from the market; (2) a recent FDA notice

---

[26] *See* Y. Dallar, et al., *Rotavirus-associated intussusception followed by spontaneous resolution*, TURK. J. GASTROENTEROL. 20(3) 209-13 (2009), filed as Pet. Ex. 23 (reporting one case of intussusception after a rotavirus infection, but also noting that the association between natural rotavirus infection and intussusception is a matter of controversy); H. Chang, et al., *Intussusception, Rotavirus Diarrhea, and Rotavirus Vaccine Use Among Children in New York State*, PEDIATRICS 108: 54-60, abstract (2001), filed as Pet. Ex. 14 (noting that intussusception and rotavirus hospitalizations had different seasonal peaks, suggesting that any causal association would be small or non-existent); L. Simonsen, et al., *Effect of rotavirus vaccination programme on trends in admission of infants to hospital for intussusception*, LANCET 358: 1224-29, 1228 (2001), filed as Pet. Ex. 15 (reporting conflicting data in other studies, but finding no increased risk).

reporting an increased risk of intussusception after Rotarix vaccine and the reports upon which this action was based; and (3) preliminary data, supplied by Dr. Halsey,[27] from a study in Australia of intussusception after RotaTeq vaccine. Doctor Thoman used this evidence in an attempt to establish biological plausibility (*Althen*'s first prong), the logical connection between Corey's vaccination and his intussusception (*Althen*'s second prong), and appropriate timing (*Althen*'s third prong).

His theory began with the premise that natural rotavirus infections cause intussusception, and thus any vaccine based on live rotavirus could be expected to do so as well. The three rotavirus vaccines that have been licensed for use in the United States (RotaShield, [28] Rotarix, and RotaTeq) are all live viral vaccines. He asserted that all three vaccines are similar, and therefore any increased risk from one could reasonably be attributed to the others. Tr. at 8-12, 15; *see also* Report of Dr. Thoman, Pet. Ex. 8. Although he acknowledged that RotaTeq vaccine was "not as troublesome" as RotaShield, he believed that because both were based on a live virus, both were capable of causing intussusception. Tr. at 20-21.

Moving from biological plausibility to the logical connection and appropriate timing between Corey's vaccination and his intussusception, Dr. Thoman acknowledged that most of the evidence showing a connection between rotavirus vaccines and intussusception implicated the first rotavirus vaccination, not the second. However, based on his experience with other vaccines and immune reactions, he indicated that some people would react to a first dose, and some might not react until the second or third dose, based on differences in immune reactions to the vaccine. Tr. at 21-22. This suggested that he considered the nature of the vaccine reaction to be one in which the first exposure leads to the development of antibodies, and the second or third exposure triggers an autoimmune or other reaction.

Doctor Thoman asserted that Corey's intussusception occurred within 14-15 days of his second vaccination.[29] Tr. at 8, 48-49. He acknowledged that most of the evidence on timing pointed to the 3-7 day period after rotavirus vaccination, and that there was no significantly increased risk during the 8-21 day period after vaccination. *See* Tr. at 48, 57. Relying to some degree on the Vaccine Injury Table's presumption of causation for live, rhesus-based rotavirus vaccines and intussusception occurring between 0-30 days after vaccination,[30] he opined that it was logical to attribute an

---

[27] *See* Res. Exs. F-L (recent (and as-yet unpublished) studies of both Rotarix and RotaTeq vaccine and intussusceptions), and discussion, *infra*.

[28] Most of the medical literature filed by petitioner and relied upon by Dr. Thoman related to RotaShield, not RotaTeq. Tr. at 37-40 (discussing specific exhibits and the vaccine to which they related).

[29] The petition in this case alleged that the first symptoms of the intussusception occurred on April 4, 2007. Petition, ¶ 5. This is 15 days after the vaccination on March 20, 2007. The diagnosis of intussusception was not made until April 7, 18 days after the vaccination. Doctor Halsey placed onset at 15-16 days post vaccination. *See* Tr. at 133.

[30] As discussed in footnote 6, the Vaccine Injury Table was amended in 2008 to remove this presumption.

intussusception occurring within 30 days of RotaTeq vaccine to the vaccine. Tr. at 16-18, 20-21. He also relied on the virus in the vaccine being attenuated to account for an incubation period significantly longer than that of the natural rotavirus, opining that it was logical that an intussusception occurring after an attenuated viral vaccine would occur up to 30 days after vaccination. Tr. at 57-58.

Doctor Thoman acknowledged that Corey had vomiting and diarrhea in conjunction with a viral illness preceding his intussusception[31] and was treated with antibiotics. Tr. at 49-50. He agreed that the medical literature supported an association between viral illnesses and antibiotic use and intussusception. Tr. at 50-51. He conceded that this viral infection "was a factor," but he believed the vaccine was the most probable cause of Corey's intussusception. Tr. at 50.

b. Overview of Opposing Views on Causation.

Respondent's experts disagreed with nearly every aspect of Dr. Thoman's opinions on causation. There was very limited agreement on biological plausibility with Dr. Halsey conceding that at the time RotaTeq vaccine was introduced, the medical community considered that it was biologically plausible that RotaTeq might cause intussusception. However, the theory by which it might do so was different from the theory advanced by Dr. Thoman, and included several important caveats. These caveats bear on the lack of a logical connection between the theory and the injury in this case, and on respondent's alternate cause case. Both the epidemiologic data and information regarding the different biological bases for the three vaccines are important in assessing whether RotaTeq, the vaccine Corey received, can cause intussusception under the circumstances present here and whether it did so in his case (the "can it cause/did it cause" formulations of the *Althen* factors).

To summarize the points of disagreement, respondent contended that any opinion based on the natural rotavirus causing intussusception was extremely weak, because, in spite of efforts to find one, no such causal connection had been established. In contrast, about 30% of intussusceptions in young children are caused by upper respiratory infections and otitis media, which Corey experienced in much closer temporal proximity to his intussusception. Respondent's experts pointed to numerous other flaws in Dr. Thoman's opinion, including his assertions of similarity among the three vaccines, his explanation for attributing risk from the first vaccination to the second, his assertion that there was an extended incubation period for attenuated viral vaccines, his extension of the epidemiologically established time frame for vaccine-caused intussusception from the first week after vaccination to the second or third week, and, most significantly, his rejection of a known cause for intussusception present in

[31] Respondent's counsel described the occurrence of this viral illness as "the week before receiving his second dose of the RotaTeq vaccine." Tr. at 49. This was likely an inadvertent misstatement. The medical records reflect that Corey suffered a viral illness, and received antibiotics, during the period between the second RotaTeq vaccination and the diagnosis of intussusception. *See, e.g.*, Pet. Exs. 5, pp. 1-2; 6, p. 20.

Corey's case in favor of a speculative one.

The evidence in this case supports the position of Drs. Halsey and Hanauer rather than that of Dr. Thoman. The opinions of the experts and the evidence in support are set forth in more detail below.

3. The Rotavirus Vaccines: Similarities and Differences.

a. RotaShield Vaccine.

All three expert witnesses testified about the RotaShield vaccine's relationship to intussusception, but Dr. Halsey's testimony was the most detailed and informative, in view of his involvement in the Phase I clinical trials of the vaccine and its withdrawal from the market. In his capacity as chair of its committee on infectious diseases, Dr. Halsey wrote the American Academy of Pediatrics ["AAP"] guidelines for both the use of RotaShield and its withdrawal from the market in 1999, about nine months after its introduction. *See* Tr. at 61-62.

Pre-licensing trials of RotaShield vaccine showed a slight risk of intussusception after vaccine versus placebo, [32] but this was not considered a significant risk until data from the Vaccine Adverse Event Reporting System ["VAERS"] signaled a possible problem. Tr. at 67-68. The VAERS reports triggered an investigation using the Vaccine Safety Datalink ["VSD"] system,[33] which found a significantly increased risk of intussusception in the three to seven day window following the first dose of Rotashield vaccine. Tr. at 48, 67-68.

A subsequent case-control study[34] looked at the timing of intussusception, post vaccination, and found no increased risk in the first two days after vaccination. This is consistent with the rotavirus incubation period. After 14 days post-vaccination, there

---

[32] This slight risk was listed by the manufacturer as a possible adverse reaction in the product insert and was included in the recommendations of the ACIP and the AAP. *See* T. Murphy, et al., *Intussusception Among Infants Given an Oral Rotavirus Vaccine*, N. ENGL. J. MED. 344(8): 564-72 (2001) ["Murphy"], filed as Res. EX. C10, at 564.

[33] The VSD system involves eight health maintenance organizations with computerized medical records. *See* P. Kramarz, et al., *Population-based study of rotavirus vaccination and intussusception*, PEDIATR. INFECT. DIS. J. 20(4): 410-16 (2001) ["Kramarz"], filed as Pet. Ex. 13 and Res. Ex. C9, at 411; *see also* J. Baggs & P. Haber, *Continued Surveillance for Intussusception (IS) following RotaTeq in VAERS and VSD*, slide presentation from Oct. 28, 2010 ACIP Meeting ["Baggs & Haber"], filed as Res. Ex. I, at 6-7. This computerized data greatly facilitates epidemiological research, as many possible causal factors and confounders can be screened quickly to examine their relationship, particularly after changes in immunization schedules or the use of new vaccines. Baggs & Haber, Res. Ex. I at 6. Doctor Halsey described the VSD system as "100 times better than the VAERS" for finding causal relationships and increased risks of vaccine injury. Tr. at 97-98.

[34] *See* Murphy, Res. Ex. C10.

was no appreciable increased risk. Tr. at 68-70. On days 3-14, there was a very significant increased risk of intussusception in vaccinated infants who had received the first dose of RotaShield vaccine.[35] Doctor Halsey explained that the clustering of cases in a particular time period after vaccination suggests a causal relationship. Tr. at 69.

Precisely how the Rotashield vaccine increased the risk of intussusception has never been determined. Doctor Halsey testified that the primary assumption in the scientific community about why RotaShield caused intussusception, but natural rotavirus infections apparently did not, had to do with the use of a rhesus-based rotavirus vaccine. RotaShield vaccine was a quadrivalent vaccine based on a rhesus monkey version of rotavirus in which three of the rhesus virus gene segments were replaced with segments of three human strains of rotavirus. Tr. at 82, 89.

b. Subsequently Licensed Rotavirus Vaccines.

Doctor Halsey testified that the risk of intussusception was "a major concern" in bringing two new rotavirus vaccines, Rotarix and RotaTeq, to the market after RotaShield's withdrawal. It was considered biologically plausible, after the RotaShield experience, that other rotavirus vaccines might cause intussusception as well. However, the manufacturers reported that they had good evidence that the new vaccines did not cause the same intestinal changes (swelling and inflammation in the intestinal wall) observed with RotaShield vaccine, which were suspected of causing the increased risk of intussusception. Tr. at 62-63, 80-81, 84-85.

(1) Rotarix Vaccine.

Rotarix is a monovalent vaccine based on a human viral strain. The initial clinical studies[36] demonstrated that the vaccine did not cause symptoms associated with naturally occurring rotaviral infections, although it contains antigens associated with about 80-90% of the wild-type rotaviruses found in the United States. Tr. at 90. In contrast, RotaShield vaccine caused symptoms such as low grade fever[37] and diarrhea, and intensive viral replication in the intestines of vaccinated infants within a few days of

---

[35] There are differences between the Kramarz study, Pet. Ex. 13, and the Murphy study, Res. Ex. C10, regarding the degree of increased risk in days 8-14 after a first dose of RotaShield. The odds ratios for both studies were computed based on prespecified periods (3-7, 8-14, etc.), rather than day by day. The day-by-day data in Fig. 1, Murphy, Res. Ex. C10, indicates that the significantly increased risk ended at day 8, although some increased risk remained through day 11. Doctor Thoman appears to have acknowledged in his testimony that the significantly increased risk ended after about day 7. *See* Tr. at 48, 57.

[36] *See* M. Patel, et al., *Intussusception and rotavirus vaccination: a review of the available evidence,* EXPERT REV. VACCINES 8(11): 1555-64 (2009), Res. Ex. C12 (reviewing safety data on Rotarix and RotaTeq vaccines).

[37] Doctor Halsey testified that fever occurred in some vaccinated infants between three and seven days post-vaccination. Tr. at 72.

vaccination. *See* Kramarz, Pet. Ex. 13 at 414; Tr. at 72, 183. Natural rotavirus infections cause gut mucosal swelling, but do not cause the lymphoid hyperplasia associated with intussusception. Tr. at 88.

(2) RotaTeq Vaccine.

The RotaTeq vaccine is based on a bovine strain of rotavirus that did not appear to cause human disease, but did not confer immunity, either. To make a vaccine capable of conferring immunity, genes from rotavirus strains that affected humans were added to it. Tr. at 82-83. The prelicensure study is summarized in Res. Ex. C13.[38] The incidence of intussusception was similar for both vaccine and placebo recipients in this study. Vesikari, Res. Ex. C13 at 23.

4. Issues with Rotarix and RotaTeq Vaccines.

a. Rotarix and Increased Risk of Intussusception.

In 2010, the FDA and the manufacturer announced a change in the package insert for Rotarix to reflect an increased risk of intussusception. *See* Res. Ex. G at 2, 16. Doctor Halsey did not learn what caused the package insert to be changed until the October, 2010 ACIP meeting, where data on studies from Mexico, Brazil, and Australia were presented. He concluded that the court should have the benefit of this information, in spite of its preliminary nature and the lack of peer review. Tr. at 91-92. Accordingly, shortly before the November 15-16 hearing, respondent filed Exs. F- L, consisting of data presented at the October, 2010 ACIP meeting, and Ex. E, a supplemental report of Dr. Halsey addressing the issues raised by the new data.[39]

Although U.S.-based studies still reflect no increased risk of intussusception from Rotarix, two independent studies performed in Mexico showed an increased risk of intussusception following a first dose of Rotarix vaccine.[40] *See* Tr. at 109-21. However, a study from Brazil was also presented at the ACIP meeting. It showed no increased

---

[38] T. Vesikari, et al., *Safety and Efficacy of a Pentavalent Human-Bovine (WC3) Reassortant Rotavirus Vaccine*, N. ENG. J. MED. 354: 23-33 (2006) ["Vesikari"].

[39] Ordinarily, the filing of additional medical literature and reports shortly before a hearing is discouraged, as such filings give the opposing party and the special master little opportunity to prepare. This case presents an example of when such filings are highly appropriate, as they represented data on vaccine risks that became available to the medical community at large only a few weeks before the hearing. Petitioner did not object to the filing of these exhibits. *See* Unopposed Mot. to File Out of Time and Notice of Filing, Nov. 9, 2010.

[40] *See* Cortese, Res. EX. H at 8 (providing (1) manufacturer's data showing a slight increased risk of intussusception in the first 30 days after administration of the first dose of Rotarix in Mexico; and (2) PATH/Pan American Health Organization/Global Alliance Vaccine Initiative study showing a clear increased risk in the 7 days after administration of the first dose of Rotarix in Mexico and a slightly increased risk in the first 21 days after the first dose); Tr. at 110-21 (discussing Mexico studies and findings).

risk of intussusception following Rotarix. Cortese, Res. Ex. H at 8; Tr. at 119. Doctor Halsey testified that he could not think of any explanation for the discordant data from Mexico, other than that there was something unique about the population studied. He noted that Mexico has a much higher background rate of intussusception in the first year of life than the U.S. Tr. at 112, 119.

b. RotaTeq and Possible Risk of Increased Intussusception.

Since the introduction of RotaTeq and Rotarix vaccines, VAERS data has been carefully monitored for an increased risk of intussusception after administration of Rotarix and RotaTeq vaccines, but no evidence of any increased risk has been observed. Tr. at 93-94. According to Dr. Halsey, VAERS data showed a "hint" of increased rates of intussusception after the first dose of RotaTeq, less after the second dose, and none after the third dose. Tr. at 99. However, the overall rate of intussusception post-vaccination reported to VAERS was less than the baseline rate expected, and thus was not reflective of any increased risk. Tr. at 99-100; *see also* Baggs & Haber, Res. Ex. I at 8 ("[finding] no evidence that RotaTeq receipt is associated with an increased risk for [intussusception] or other pre-specified adverse events"). Doctor Halsey noted that VAERS has some inherent difficulties that preclude its use to establish causality,[41] but the hints, coupled with the RotaShield experience, prompted the use of the VSD to examine data in a more controlled manner.

Two years of VSD data showed "no evidence that RotaTeq receipt is associated with an increased risk for [intussusception] or other pre-specified adverse events." Cortese, Res. Ex. I at 8. However, as Dr. Halsey pointed out, the number of cases of intussusception was so small that the study did not have enough power to detect a two-fold increased risk of intussusception, if one existed. Tr. at 104-05. He also noted that this preliminary data was based on unconfirmed reports of intussusception. Tr. at 100. Post-licensure marketing studies performed in the United States showed no increased risk of intussusception from either Rotarix or RotaTeq vaccines. Tr. at 93-94, 109; *see also* Res. Ex. F at 7;[42] Res. Ex. J at 7.[43]

---

[41] VAERS problems include underreporting. In response, an effort was made to encourage primary care physicians to report intussusceptions. Tr. at 93. Because anyone can make a VAERS report, publicity about a possible vaccine-related injury can stimulate reporting, skewing data. The type of disorder also affects reporting rates; more severe disorders have higher reporting rates. Disorders that occur in close temporal proximity to a vaccination (about one week post-vaccination) are more likely to be reported to VAERS than those that occur later. Tr. at 94-95, 98. For these, among many other reasons, VAERS data is considered inadequate to establish causality. *See, e.g.*, *Donica v. Sec'y, HHS*, No. 08-625V, 2010 WL 3735707, at *11 (Fed. Cl. Spec. Mstr. Aug. 31, 2010) (citing *Analla v. Sec'y, HHS*, 70 Fed. Cl. 552, 558 (2006)).

[42] L. Chilton, *Rotavirus Vaccine – New Information*, slide presentation from Oct. 28,2010 ACIP Meeting, filed as Res. Ex. F.

[43] T. Mast, *Postlicensure Safety Study for RotaTeq Review of Intussusception (IS) Data*, slide presentation from Oct. 28, 2010 ACIP Meeting ["Mast"], filed as Res. Ex. J.

However, preliminary data from Australia reflect a significantly increased risk of intussusception in the first seven days following administration of the first dose of RotaTeq vaccine in children age one to three months. *See* J. Bines & J. Buttery, *Post-marketing surveillance for Rotavirus Vaccines in Australia*, slide presentation from Oct. 28, 2010 ACIP Meeting, filed as Res. Ex. L, at 9.[44] There was no increased risk after the second dose. *Id.*; Tr. at 125-26. These findings of an increased risk of intussusception with RotaTeq conflict with both VSD and manufacturer's studies in the United States showing no increased risk following the administration of the first dose of RotaTeq. Cortese, Res. Ex. H at 9. Doctor Halsey explained that, in addition to being preliminary, the Australian data showing an increased risk was based on comparisons with historical rates of intussusception. Because there can be variations in intussusception rates from year to year,[45] historical data is less reliable as a control than using concurrent recipients of other vaccines or unvaccinated children as controls. Tr. at 126-29.

5. Evaluation of Petitioner's Causation Case.

a. *Althen*'s Prong 1.

At best, petitioner demonstrated that it is biologically plausible for a rotavirus vaccine to cause an intussusception, and that the data on RotaTeq's propensity to do so is in conflict. However, the weight of the evidence is that RotaTeq does not cause intussusception. Controlled, published, and peer reviewed studies pertaining to U.S.-based populations are more persuasive as evidence than preliminary, unpublished data from Australia finding an increased risk based on historical intussusception rates for comparison. Although the U.S. studies[46] finding no evidence of any increased risk of intussusception after any dose of RotaTeq vaccine do not have sufficient power to rule out a twofold greater risk, it is petitioner's burden to demonstrate that RotaTeq can cause intussusception, not respondent's burden to rule it out. Although Dr. Halsey conceded that a relationship between RotaTeq and intussusception was considered plausible when RotaTeq was in development, he did not think a true causal relationship had been established or was likely. Tr. at 131-32, 144-46.

If there is a small increased risk of intussusception after RotaTeq, the risk exists only after the first dose of the vaccine and only for the first seven days after vaccination. Tr. at 132-33. In this case, however, petitioner's theory of causation appears to be unconstrained. Doctor Thoman took the position that if one type of a rotavirus vaccine

---

[44] The markings on the electronically filed slides erroneously reflect that they are Res. Ex. K.

[45] For example, variance in intussusception rates in the U.S. is shown on Mast, Res. Ex. J at 8. If intussusception is caused by lymphoid aggregates swelling in response to exposure to pathogens, the rate would be expected to vary by year, as many disease rates vary from year to year.

[46] *See* Tr. at 101-06, 109.

can cause intussusception, then any rotavirus vaccine can do so, up to 30 days post-vaccination. I reject that position. The only reliable evidence that any rotavirus vaccine can cause intussusception is limited to the first dose and to intussusceptions occurring in the first 3-7 days after that vaccination, with a slightly elevated risk for RotaShield extending out to 14 days.[47]

The RotaShield experience provides little support for petitioner's causation case. The two vaccines are biologically distinct: RotaShield was based on a rhesus monkey virus and RotaTeq was based on a bovine rotavirus strain that did not cause human disease. Tr. at 82-84. RotaShield caused fever; RotaTeq does not cause fever, diarrhea, or vomiting. Tr. at 72-73.

b. *Althen*'s Prongs 2 and 3.

Assuming, *arguendo*, that RotaTeq can cause intussusception, the Australian data suggests that it does so only under limited conditions—only after the first vaccination, and only within the first week after that vaccination. Based on these caveats, petitioner cannot logically connect Corey's second RotaTeq vaccination to his intussusception, nor can she establish medically appropriate timing.

Doctor Halsey persuasively rebutted Dr. Thoman's assertion that the incubation period would be longer in an attenuated viral vaccine than in a naturally occurring viral infection. Doctor Halsey's testimony demonstrated that this assertion was contrary to medical experience with vaccines. *See* Tr. at 72-74. In this regard, I note Dr. Halsey's considerable academic qualifications and clinical experience with both vaccines and infectious diseases. He testified that with RotaShield vaccine, the fever occurred within one or two days of vaccination (Tr. at 72), a period similar to that of the natural rotavirus incubation period (Tr. at 57-58, 191). In other attenuated viral vaccines, the incubation period is either the same as or shorter than that of the natural virus, because injection of the attenuated virus serves as a shortcut for some of the viral replication processes. Doctor Halsey pointed to the measles vaccine's shorter incubation period than that of natural measles infections. Tr. at 73-74. He testified that he was unaware of any vaccine, viral or bacterial, in which there was a longer incubation period over that of the natural infection. Tr. at 74. Doctor Halsey's testimony was consistent with evidence about measles virus and measles vaccine developed in other cases. *See, e.g*., *Snyder*

---

[47] To the extent that Dr. Thoman relied on the time period on the Vaccine Injury Table for intussusception following RotaShield as evidence that a similar time period should apply to Rotarix or RotaTeq, I find his reliance to be misplaced. *See Moberly*, 592 F.3d at 1323: "As this court has stated, 'neither a mere showing of a proximate temporal relationship between vaccine and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation.' *Althen*, 418 F.3d at 1278. That is true even if the off-Table injury occurs within a time period set forth in the Table." In *Moberly*, the Federal Circuit cited to H.R. Rep. No. 98-908, part of the legislative history of the Vaccine Act, in support. "Simple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner [bringing a causation in fact claim]." H.R. Rep. No. 98-908, pt. 1, at 15 (1986), *reprinted in* 1988 U.S.C.C.A.N. 6344, 6356.

*v. Sec'y, HHS*, No. 01-162V, 2009 WL 332044, at *96-99 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).

Doctor Halsey also successfully countered Dr. Thoman's testimony extrapolating an increased risk after the first dose of RotaShield and Rotarix to an increased risk after subsequent doses. The increased risk after the initial dose has a biological and physiological basis. If the vaccine represents a first exposure to the virus, a greater immune response would be expected as the immune system learns how to fight the virus. This initial exposure would therefore cause more swelling in lymphoid tissue. This tissue swelling is the likely cause of intussusception, creating a leading edge for the telescoping of the intestine. Because the first vaccine also confers some protection against the virus, the immune response is lessened in the second and third vaccinations, causing less swelling. *See* Tr. at 129-30. This is consistent with the measles vaccine experience, in which a febrile reaction occurs after the first measles vaccine, but not after the second. Tr. at 130. This explanation is also consistent with the epidemiologic data on RotaShield and with the data from Mexico on Rotarix.[48] An increased risk was observed within 3-7 days after the first rotavirus vaccination, but there was no evidence of an increased risk after the second rotavirus vaccination.

In summary, Corey's intussusception occurred too long after the wrong dose of RotaTeq vaccine to meet the very limited circumstances under which a RotaTeq vaccine might possibly be considered causal. Thus, petitioner's case fails to meet the *Althen* criteria for demonstrating actual causation.

6. Alternate Cause for Corey's Intussusception.

a. Law Pertaining to Alternate Cause.

In the prehearing submissions, the parties set forth their disagreement concerning whether evidence of alternate cause can be used to defeat a prima facie case. Petitioner asserted "evidence of potential alternate causes should not be considered when evaluating the Petitioner's prima facie cause in fact case. She believes that this evidence is relevant only to the Respondent's factor unrelated defense." Joint Submission, filed Nov. 1, 2010, at 4 (emphasis original).

Petitioner's position that evidence of alternate cause may not be used to rebut petitioner's cause in fact case is legally flawed. However, in this case, the outcome would be the same, even if I followed petitioner's view of the law.

---

[48] I note that in Vaccine Act cases in which the causation case is based on the molecular mimicry theory, in which some vaccine component is homologous (shares certain genetic sequences) with body tissue, it is the second or third vaccine that triggers the onset or the aggravation of an autoimmune disease. *See Hennessey v. Sec'y, HHS*, No. 01-190V, 2009 WL 1709053, at *25 (Fed. Cl. Spec. Mstr. May 29, 2009) (explaining molecular mimicry as it applies to vaccine causation), *aff'd.*, 91 Fed. Cl. 126 (2010). In this case, it is the direct immune response occurring in lymphoid tissue, causing that tissue to swell, that is implicated, not autoimmunity.

In an off-Table case, petitioners do not automatically shift the burden to respondent to prove an alternate cause merely by offering an opinion of a medical expert. Respondent may challenge the factual underpinnings of a causation opinion, the opinion itself, or both. *See de Bazan*, 539 F.3d at 1353-54. If the special master concludes that petitioner's evidence of causation is lacking, then the burden never shifts to respondent to demonstrate the "factors unrelated" as an alternative cause for petitioner's injury. *See Bradley v. Sec'y, HHS*, 991 F.2d 1570, 1575 (Fed. Cir. 1993) (when petitioner has failed to demonstrate causation by a preponderance, alternative theories of causation need not be addressed); *Johnson v. Sec'y, HHS*, 33 Fed. Cl. 712, 721-22 (1995) (even in idiopathic disease claims, the special master may conclude petitioner has failed to establish a prima facie case), *aff'd*, 99 F.3d 1160 (Fed. Cir. 1996). In *de Bazan*, the Federal Circuit explicitly stated that the special master may consider all of the evidence presented, including that of respondent, in determining whether petitioners have met their burden of proof. 539 F.3d at 1353-54.

b. Evaluation of Respondent's Alternate Causation Case.

Evidence of an alternate cause for Corey's intussusception is an additional reason to reject petitioner's causation claim, and one that is sufficient, standing alone, to find against petitioner. While I have found that petitioner did not demonstrate a prima facie case, I further find that even if she did so, respondent has successfully demonstrated cause by a factor unrelated, Corey's upper respiratory infection, under § 300aa-13(a)(1)(B).

As Special Master Moran has observed, *Knudsen* requires that "'the standards that apply to a petitioner's proof of actual causation in fact in off-table cases should be the same as those that apply to the government's proof of alternative actual causation in fact.'" *Heinzelman v. Sec'y, HHS*, No. 07-01V, 2008 WL 5479123, at *17 (Fed. Cl. Spec. Mstr. Dec. 11, 2008), *mot. for rev. docketed* (Fed. Cl. Jan. 6, 2011) (quoting *Knudsen*, 35 F. 3d at 549). *Knudsen* thus likely requires respondent to satisfy the *Althen* framework for analyzing and evaluating causation evidence. *See id.* Respondent is further required to demonstrate that the factor unrelated was "principally responsible" for causing Corey's injury. § 300aa-13(a)(2)(B); *see also Stone v. Sec'y, HHS*, 95 Fed Cl. 233, 237 (2010) (citing *de Bazan*, 539 F.3d at 1354).

Respondent produced preponderant evidence under *Althen* that Corey's intussusception was caused by his upper respiratory infection ["URI"]. Respondent's experts provided a medical theory by which URI can cause intussusception, successfully linked Corey's illness to his URI, and demonstrated that the timing of his intussusception was consistent with the time frame expected after the onset of his URI. Thirty percent of intussusceptions are associated with antecedent upper respiratory illnesses in children, demonstrating that a URI can cause intussusception. *See* Tr. at

186-87, 190.[49] Dr. Thoman conceded this point. Tr. at 50-51.

According to both Drs. Halsey and Hanauer, the most probable cause for Corey's intussusception was the URI he had for several days preceding the intussusception and the antibiotics prescribed to treat it. *See* Res. Ex. A at 2-3; Tr. at 133-35, 182-83; *see also* D. Spiro, et al., *Association Between Antibiotic Use and Primary Idiopathic Intussusception*, ARCH. PEDIATR. ADOLESC. MED. 157: 54-59 (2003), filed as Res. Ex. A3, at 56-57 (finding an increased risk of intussusception following the use of penicillin antibiotics, which can cause small bowel disturbances). Of course, the fact that URI is statistically more likely to cause intussusception than the RotaTeq vaccine does not mean that Corey's URI did so in this case. *See Knudsen*, 35 F.3d at 550. But URIs, and the use of amoxicillin to treat them, are common causes of diarrhea (Tr. at 182), which interferes with gut motility. In Dr. Hanauer's words, Corey's ear infection "really whipped up his immune system." Tr. at 183. The infection and the amoxicillin likely caused the lymphoid aggregates in Corey's intestine to swell. This in turn caused the prolapse of the small intestine into the colon, producing the intussusception. This sequence of events provides the logical sequence of cause and effect between Corey's URI and intussusception. The medically appropriate timing between the URI and the intussusception bolsters respondent's theory. Tr. at 132-33, 183.

I find preponderant evidence that Corey's intussusception was caused by his antecedent illness and the antibiotics used to treat it.

B. Residual Effects or Complications.

In her report pursuant to Vaccine Rule 4, respondent raised the issue whether Corey experienced effects from his intussusception for longer than the statutory requirement of six months.[50] We then discussed this issue in the Vaccine Rule 5 status conference on May 24, 2010, and on May 25, 2010, I ordered petitioner to file a brief and, as necessary, any medical opinions addressing whether an increased risk of developing a second intussusception is a residual effect or complication of intussusception.

In her July 15, 2010 response to my order, petitioner filed a memorandum setting

---

[49] I note, too, that there is no evidence that the RotaTeq vaccine caused the ear infection and diarrhea, and it would have been biologically implausible for it to have done so, as there were more than 10 days between vaccination and the onset of the upper respiratory infection. *See* Tr. at 183, 190.

[50] The statutory provision set forth in § 300aa-11(c)(1)(D), requires that the vaccinee:

> (i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention.

forth her case that "[a]n infant who suffers an episode of intussusception is at increased risk of intussusception for about 36 months." Petitioner's Memorandum ["Pet. Mem."] at 3. Respondent filed a memorandum on August 6, 2010, contending that an "increased risk," or the possibility "that Corey *might* experience a future recurrence of intussusception," does not satisfy the statutory requirement. Respondent's Memorandum ["Res. Mem."] at 1 (emphasis original). Petitioner filed a reply on August 23, 2010.[51] Both parties also addressed this issue in their post-hearing briefs ["Pet. Post-Hearing Br." and "Res. Post-Hearing Br.," respectively].

Petitioner argued that Corey was at an "increased risk" of suffering a second intussusception, and that this increased risk constituted a residual effect under the Act. Pet. Mem at 3. Petitioner further argued that Corey's hospitalization and x-ray in August, 2008 were residual effects of the alleged vaccine injury, even though doctors determined that Corey had not suffered a second intussusception. Pet. Post-Hearing Br. at 18. Respondent argued that the plain language of the Act and its intent and purposes as set forth in the legislative history establish that an increased risk of possible injury is not compensable under the Act. Res. Mem. at 5, 9; Res. Post-Hearing Br. at 23, 27. Citing to other Vaccine Act cases interpreting § 300aa-11(c)(1)(D),[52] respondent argued that this subsection manifested an intent to compensate only serious injuries. Res. Mem. at 9. I conclude that petitioner has not satisfied the six month requirement.

1. The Plain Language of the Act.

To resolve this dispute, I begin with the pertinent language of the Vaccine Act as originally drafted and as subsequently amended. *See Flowers v. Sec'y, HHS*, 49 F.3d 1558, 1560 (Fed. Cir. 1995) ("statutory interpretation begins with the language of the statute itself, which must ordinarily be regarded as conclusive absent a clearly expressed legislative intent to the contrary"). While this provides a useful starting point, ultimately the plain language of the statute alone does not provide clear guidance.

The statute requires that Corey must have "suffered the residual effects or complications" of his intussusception "for more that 6 months after the administration of the vaccine." § 300aa-11(c)(1)(D)(i). The terms "residual effects" and "complications" are not further defined in the Act. However, in the context of the Vaccine Act subsection in which they appear, "complication" and "residual effects" are medical terms, and thus I turn first to a medical dictionary to define them. *See Abbott v. Sec'y, HHS*, 27 Fed. Cl. 792, 794 (1993) ("Congress intended this statute to be understood—and to be applied—as it would be by a medical professional."), *rev'd on other grounds*, 19 F.3d 39 (Fed Cir.

---

[51] While I initially anticipated resolving this issue prior to a hearing on entitlement (*see* Order filed May 25, 2010), I subsequently informed the parties at a September 16, 2010 status conference that the nature of the parties' submissions prompted me to delay ruling until after I had heard the expert testimony.

[52] *See Ionescu v. Sec'y, HHS*, No. 88-64V, 1989 WL 250134, at *6-7 (Cl. Ct. Spec. Mstr. Oct. 19, 1989); *Newman v. Sec'y, HHS*, No. 88-17V, 1989 WL 250112, at * 8 (Cl. Ct. Spec. Mstr. Sept. 1, 1989).

1994). "Complication" is defined as "disease or diseases concurrent with another disease" or as "the concurrence of two or more diseases in the same patient." DORLAND'S at 404. "Residual" is defined as "remaining or left behind." *Id*. at 1650. "Effect" is defined as "the result produced by an action." *Id*. at 601. "Residual effect" would therefore refer to something left behind or resulting from an illness, disability, injury, or condition. Neither term would appear to encompass the *possibility* of an ill effect remaining after an intussusception. Nor would they appear to encompass treatment and diagnosis of an unrelated illness.

The witnesses provided some guidance on how a medical professional would interpret "residual effects" under the Act. When asked whether Corey suffered "residual effects of his intussusception," Dr. Thoman cited studies demonstrating increased risk of a second intussusception, and noted Corey's August, 2008 emergency department visit for gastroenteritis. Tr. at 22. This answer suggests that Dr. Thoman would associate the intussusception with an increased risk and with the emergency department visit, but he did not opine that these constituted "residual effects" as used by medical professionals. He did not evince an appreciation of a distinction between an association and a relationship sufficient to demonstrate "residual effects" under the statute.

Doctor Halsey testified that a risk of recurrence is not the same as a residual effect of a condition, suggesting that something more concrete would be required. Tr. at 141. Doctor Hanauer also testified that Corey did not experience any ongoing effects of his intussusception. Tr. at 186. In his expert report, Dr. Hanauer opined that "[t]here were no residual effects of … the intussusception." Res. Ex. A at 2. He noted the August, 2008 hospitalization and the absence of evidence at that time of a second intussusception, concluding "[t]he likelihood of recurrent intussusception subsequent to this timeframe is negligible." *Id.*

Both Dr. Halsey and Dr. Hanauer attributed any increased risk of a second intussusception to the underlying factors that predisposed the patient to an intussusception in the first place, not the first intussusception itself. *See* Tr. at 140-41, 185-86. In other words, an external cause for a first intussusception would not be causal of a second intussusception, absent a recurrence of the external cause. The second intussusception would be attributable to the underlying intestinal structural problems, given that a high percentage of intussusceptions in infants and young children are idiopathic, or possibly, attributable to an infection that aggravated those structural defects. *Id.*; *see also* Kitigawa, Res. Ex. A1 at 1 (noting the idiopathic nature of most intussusceptions). Doctor Hanauer explained that the risk of reoccurrence is highest soon after the first intussusception, because "it's the same process" that is causal, and the risk "peters out" over time. Tr. at 186.

2. Evolution of the Act.

If the language of the statute, with its terminology defined by medical professionals, is insufficient to resolve this issue, the evolution of the Vaccine Act in general, and of the pertinent subsection in particular, may prove informative.

Respondent points to Congressional concern about serious injury, demonstrated in the Act and the legislative history, in arguing that the possibility of injury is insufficient to extend the term of Corey's injury beyond the short recovery period after his barium enema. *See* Res. Mem. at 9-10.

There is certainly some support for respondent's position, both in the Act and in its legislative history. Originally, § 300aa-11(c)(1)(D) of the Vaccine Act required petitioners to prove that they suffered residual effects or complications of a vaccine injury for longer than six months and had incurred more than $1,000 in unreimbursable expenses. Clearly, Congress did not intend compensation for transient vaccine injuries, such as the fever and malaise children commonly experience after routine childhood immunizations. The requirement that injuries persist longer than six months speaks to this intention, as does this out-of-pocket expense requirement.

The legislative history supports this reading. The House of Representatives' committee report indicates that "the effect of [§ 300aa-11(c)(1)(D)] is to limit the availability of the compensation system to those individuals who are seriously injured from taking a vaccine." H.R. Rep. No. 391-100, at 699 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-373. It also describes the six month provision as requiring a person "suffer[] ongoing disabilities" (*id.*), suggesting that the committee viewed a residual effect as more concrete than increased risk.

In practice, the $1,000 provision proved problematic, in that the expenses had to be incurred before the petition was filed. *See, e.g.*, *Black v. Sec'y, HHS*, 93 F.3d 781 (1996). Thus, someone with good insurance and serious injury might not be entitled to compensation, despite a lifetime of vaccine injury related expenses incurred after the petition was filed. In 1998, the unreimbursable expenses provision was struck from the Act. *See* Omnibus Appropriations Act, Pub. L. No. 105-277, § 1502, 112 Stat. 2681, 2681-741(codified as amended at 42 U.S.C. § 300aa-11(c)(1)(D)).

In the Act as originally written, there was no surgical exception to the six month rule. However, in 2000, in response to the development of evidence that the RotaShield vaccine presented an increased risk of intussusception, Congress amended § 3000aa-11(c)(1)(D) of the Vaccine Act to require petitioners to establish: (i) that they met the six-month requirement, or (ii) that the vaccinee had died, or (iii) that the vaccine injury necessitated inpatient hospitalization and surgery. *See* Children's Health Act, Pub. L. No. 106-310, § 1701, 114 Stat. 1101, 1151 (2000) (codified as amended at 42 U.S.C. § 300aa-11(c)(1)(D)) ["2000 Amendment"]. The new subsection (iii) was added to address RotaShield and intussusception. As the legislative history of this amendment reflects:

> Recently, however, a new situation has developed that was not foreseeable at the time of enactment of this law. In October 1999, the CDC's Advisory Committee on Immunization Practices (ACIP), after a review of scientific data from several sources, concluded that intussusception occurs with significantly increased frequency in the first 1-

> 2 weeks after vaccination for rotavirus, particularly after the first dose….
>
> While most cases of intussusception require only minimal treatment, a few cases require hospitalization and surgery. Under the current law, these cases would not be compensable by the United States Claims Court under the Vaccine Injury Compensation Program, since the statute grants jurisdiction to resolve vaccine cases only in instances in which claimants have suffered the residual effects or complications of a vaccine-related injury for at least six months, or died from the administration of a vaccine.
>
> For this reason, we are offering this bill to amend the law and grant jurisdiction to the Claims Court to resolve compensation cases under the Program in cases in which both hospitalization and surgical intervention were required to correct the "illness, disability, injury or condition" caused by the vaccine.

145 CONG. REC. 31210 (1999).

If an increased risk of a second intussusception were sufficient to constitute a "residual effects or complication" of a vaccine-caused intussusception, there would have been no need for the 2000 amendment adding the exception for inpatient hospitalization and surgery. Every child who experienced an intussusception was at some increased risk of a second, although there was a slightly higher risk for those treated by barium enema rather than surgery. *See* Tr. at 22.

I note that after surgery to reduce an intussusception, a child would have a scar. If I adopt the expansive reading of the term that petitioner urges, the scar could constitute a persistent "residual effect" of the surgery necessitated by a vaccine-caused intussusception. By this construction, the 2000 Amendment would have been unnecessary, as the scar from surgery could have served as the residual effect lasting for more than six months.

3. Program Case Law.[53]

Petitioner noted that the two Vaccine Act cases that address the issue of duration of residual effects provide little guidance. *See Vant Erve v. Sec'y, HHS*, No. 92-341V, 1994 WL 325426 (Fed. Cl. Spec. Mstr. Jun. 21, 1994), *rev'd on other grounds*, 39 Fed.

---

[53] In her memorandum, petitioner looks outside the Program for guidance, suggesting that the issue be analyzed in terms of whether an increased risk of harm confers standing to seek damages for medical monitoring, citing to *Sutton v. St. Jude Medical S.C., Inc.*, 419 F.3d 568 (6th Cir. 2005). Pet. Mem. at 3-4. Respondent argues that the non-Vaccine Act cases involving standing to bring claims for future injury are inapplicable. Res. Mem. at 12. The plain language of the Act, the legislative history, and Program cases are sufficient to resolve this issue. Accordingly I decline to adopt petitioner's analysis under non-Program cases.

Cl. 607 (1997)[54]; *Toebe v. Sec'y, HHS*, No. 91-1623V, 1992 WL 101638 (Fed. Cl. Spec. Mstr. Apr. 23, 1992). In *Toebe*, a case presenting a claim of a residual seizure disorder, the vaccinee took medication for several months after experiencing seizures attributed to a vaccination. The special master concluded that the vaccinee had not suffered the residual effects of the vaccine injury because she did not experience seizures or other sequelae of her seizure disorder six months or more after her injury. The special master concluded that taking anti-seizure medication, and experiencing its attendant "[t]ransient" side effects, were insufficient to meet the requirement. *Toebe*, 1992 WL 101638, at *3. The special master added that even though the medication "may have blocked seizures which would have otherwise occurred, a finding that it did could only be based on speculation." *Id.* In *Vant Erve*, also a residual seizure disorder case, the vaccinee's behavior and development were changed after the initial seizures, but he did not have additional seizures. The special master concluded that this change in behavior and development, attributable to the vaccine-related seizures, was sufficient to meet the six month requirement. *Vant Erve*, 1994 WL 325426, at *4.

I agree with petitioner that these cases are not controlling. Petitioner is correct that they do not "approach[] the issue by asking whether a risk of future [injury] was a "residual effect" of the initial [injury]," Pet. Mem. at 3. Thus, they do not address the specific issue in this case.

In *Toebe*, there were no lasting injuries to the vaccinee—she, in effect, made a full recovery. In *Vant Erve*, however, the vaccine-related seizures caused the ultimate, lasting changes in the vaccinee's behavior and development. These findings are not in conflict, they are distinguishable on the facts presented, and they are consistent with my conclusion here. Like the *Toebe* vaccinee, Corey made a complete recovery. His "increased risk" of suffering a second intussusception is analogous to the possibility that the *Toebe* vaccinee could have suffered further seizures--"a finding that … could only be based on speculation." *See Toebe*, 1992 WL 101638, at *3. Unlike the *Vant Erve* vaccinee, Corey's injury did not permanently alter his health, or even alter his health for a period extending beyond the six month time frame. While two of the three experts in this case opined that Corey's hospitalization in August, 2008 was likely a precaution informed by his history of intussusception, the records confirm that the gastroenteritis he suffered at that time was not a sequela of his intussusception, and none of the experts opined otherwise.

4. The August, 2008 Hospitalization.

Corey returned to the HRMC emergency room with vomiting and mild diarrhea on August 6, 2008. Pet. Ex. 7, p. 1. His history of intussusception was noted along with

[54] The lengthy subsequent history of this case overruled the special master's determination of entitlement, finding that respondent had demonstrated cause by a factor unrelated. *See Vant Erve v. Sec'y, HHS*, 232 F.3d 914 (Fed. Cir. 2000). The appellate review did not find fault with the special master's analysis of the six month requirement. While the injury in that case was ultimately found not to be "vaccine caused," I refer to it as such in this discussion for ease in illustrating the six month requirement.

other significant health history unrelated to gastrointestinal problems. *Id.*at 1, 11. An abdominal x-ray was performed in the emergency department and revealed no sign of intussusception (id. at 17), effectively ruling out a second intussusception. *See* Tr. at 53-55. Corey was thereafter admitted overnight for observation and discharged the next morning. Id. at 1, 17-18.

The experts disagreed whether the overnight observation was the appropriate standard of care for Corey. Doctor Thoman "would agree…to err on the side of caution," and called the overnight observation "judicious." Tr. at 22, 53. He added that "[i]f I were the medical director of that hospital, I certainly wouldn't have criticized it." Tr. at 53. Doctor Hanauer described the hospitalization as "very much a clinical decision based on his status at that time." He added that it was a "reasonable precaution" and a "conservative approach." Tr. at 192-93. Doctor Halsey opined that it was unnecessary, and not the standard of care in his experience, to admit Corey for observation of "mild gastroenteritis." Tr. at 141-42.

Petitioner argues that the hospitalization and the x-ray were "the result of, and therefore a residual effect of" Corey's intussusception. Pet. Mem. at 18. This argument suggests a but-for analysis of residual effects that is inconsistent with the language of the statute, the legislative history, and cases interpreting the term. I reach this conclusion for the same reasons that an "increased risk" is not a residual effect. Diagnosis and treatment of symptoms that are not attributable to the injury are not residual effects of the injury.

5. Petitioner has failed to establish that Corey suffered the residual effects of his injury for more than six months.

The language of the statute, as illuminated by the legislative history and case law, indicates that an increased risk of a second intussusception and the August, 2008 hospitalization, are not residual effects of the initial intussusception. Unfortunately it appears that Corey's injury, if it were vaccine-caused, is one that Congress determined was not sufficiently serious to merit compensation under the Act. This does not diminish the seriousness of Corey's initial illness. It does illustrate, however, that in creating the Program, Congress distinguished injuries that resolve from those that persist. Even if petitioner had demonstrated causation in fact, she has failed to demonstrate residual effects of the injury persisted for more than six months.

## IV. Conclusion.

Petitioner has not demonstrated by a preponderance of the evidence that Corey's intussusception was caused in fact by the RotaTeq vaccination he received on March 20, 2007. Petitioner has also not demonstrated that Corey suffered the residual effects of the intussusception for more than six months. The petition for compensation is therefore **DENIED**. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk is directed to enter judgment accordingly.

**IT IS SO ORDERED.**

**s/Denise K. Vowell**
**Denise K. Vowell**
Special Master